GOVERNMENT OF INDIA
SCIENCE AND TECHNOLOGY
LOK SABHA

UNSTARRED QUESTION NO:2829
ANSWERED ON:11.05.2016
Medicines Manufactured through Bio-Technology
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Will the Minister of SCIENCE AND TECHNOLOGY be pleased to state:

(a) whether the Government has reviewed the side-effects, if any, of the use of medicines manufactured through biotechnology;

(b) if so, the details and the outcome thereof;

(c) whether the Government has constituted any team of experts for assessing the impact of use of the said medicines on the supply of generic drugs;

(d) if so, the details thereof and the outcome therefrom;

(e) whether the kit called AINA is to be marketed shortly; and

(f) if so, the details of the benefits of this kit and cost at which it is available / likely to be made available to the general public alongwith the other innovations likely to be put in the market developed by the Department of Biotechnology?

Answer

MINISTER OF STATE FOR SCIENCE & TECHNOLOGY AND EARTH SCIENCES
(Y. S. CHOWDARY)

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(???. ??. ?????)

(a)& (b)Yes, Madam. The safety of medicines manufactured through biotechnology is reviewed during Phase-I to Phase-III clinical trials depending on the nature of medicine i.e. new biological entity or biosimilar. Marketing authorization is granted after successful completion of Phase-III clinical trials. Subsequent pharmacovigilance studies are also reviewed to continue market authorization. So far no medicine manufactured through biotechnology is withdrawn during pharmacovigilance studies.

(c) No Madam.

(d) Does not arise.

(e)&(f) AINA a diagnostic kit has been developed by Janacare Solutions Pvt. Ltd., New Delhi, with partial funding by Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Unit of the Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India and is currently under validation for commercialization. This kit is meant for measuring blood glucose, HbA1C, lipids (HDL, LDL, TrG), creatinine and hemoglobin. DBT and BIRAC are supporting large number of innovations in Research Institutes, Start-ups and SMEs which are currently under different stages of development and clinical validation for commercialization.
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